

PTO/SB/06a (10-07)

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Substitute for form 1449A/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		Application Number	10/525,958
		Filing Date	October 20, 2005
		First Named Inventor	Robert CASPER
		Art Unit	2873
		Examiner Name	Pinkney, D.
		Attorney Docket Number	101648.55960US
(Use as many sheets as necessary)			
Sheet	1	of	9

U.S. PATENT DOCUMENTS					
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/DP/	A2	US- 2006/0119954	A1 06-08-2006	Casper et al.	
	A3	US- 5,304,212	A 04-19-1994	Czeisler et al.	
	A4	US- 6,638,963	B1 10-28-2003	Lewy et al.	
	A5	US- 6,156,743	A 12-05-2000	Whitcomb	
	A6	US- 4,878,748	11-07-1989	Johansen et al.	
		US-			
		US-			
		US-			

FOREIGN PATENT DOCUMENTS					
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

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## NON PATENT LITERATURE DOCUMENTS

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/DP/	C4	AKERSTEDT, T. et al., "Alertness-enhancing drugs as a countermeasure to fatigue in irregular work hours", <i>Chronobiol Int</i> , 1997, Vol. 14, pp. 145-158.	
	C5	ARAI, Y. et al., "Critical exposure time for androgenization of the developing hypothalamus in the female rat", <i>Endocrinology</i> , Vol. 82, pp. 1010-1014, 1968.	
	C6	ARMOUR, D. et al., "Melatonin in the treatment of insomnia in children and adolescents", <i>Psychiatric Bulletin</i> , (2004), Vol. 28, pp. 222-224.	
	C7	BARKER, D., "In utero programming of chronic disease" <i>Clin Sci</i> , Vol. 95, pp. 115-128, 1998.	
	C8	BARKER, D.J. et al., "Fetal nutrition and cardiovascular disease in adult life", <i>Lancet</i> , Vol. 341, pp. 938-941, 1993.	
	C9	BARRENETXE, J. Et al., "Physiological and metabolic functions of melatonin", <i>J Physiol Biochem</i> , 2004, Vol. 60, pp. 61-72.	
	C10	BENEDIKTSSON, R., "Glucocorticoid exposure in utero: new model for adult hypertension", <i>Lancet</i> , Vol. 341, pp. 339-341, 1993.	
	C11	BENLOUCIF, S. et al., "Interactions between light and melatonin on the circadian clock of mice", <i>J Biol Rhythms</i> , 1999, Vol. 14, pp. 281-8.	
	C12	BENSHOFF, H.M. et al., "Suppression of pineal melatonin in <i>Peromyscus leucopus</i> by different monochromatic wavelengths of visible and near-ultraviolet light (UV-A)", <i>Brain Res</i> , 1987, Vol. 420, pp. 397-402.	
↓	C13	BLASK, D.E. et al., "Melatonin-depleted blood from premenopausal women exposed to light at night stimulates growth of human breast cancer xenografts in nude rats", <i>Cancer Res</i> , 2005, Vol. 65, pp. 11174-84.	
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/DP/	C14	BLASK, D.E. et al., "Growth and fatty acid metabolism of human breast cancer (MCF-7) xenografts in nude rats: impact of constant light-induced nocturnal melatonin suppression", <i>Breast Cancer Res Treat.</i> , 2003, Vol. 79, pp. 313-20.	
	C15	CAJOCHEN, C. et al., "High Sensitivity of Human Melatonin, Alertness, Thermoregulation, and Heart Rate to Short Wavelength Light", <i>J Clin Endocrinol Metab.</i> , 2005, Vol. 90, No. (3), pp. 1311-1316.	
	C16	COLLIGAN, M.J. et al., "Shiftwork: Effects of social and family life. Shiftwork: Occupational Medicine" <i>State of the Art Reviews</i> , 1990, Vol. 5, No. (2), pp. 315-322.	
	C17	CZEISLER, C.A. et al., "Exposure to bright light and darkness to treat physiologic maladaptation to night work", <i>N Engl J Med</i> , 1990, Vol. 322, pp. 1253-1259.	
	C18	CZEISLER, C.A. et al., "Bright light induction of strong (type 0) resetting of the human circadian pacemaker", <i>Science</i> , 1989, Vol. 244, pp. 1328-1333.	
	C19	DAWSON, D. et al., "Timed exposure to bright light improves sleep and alertness during simulated night shifts", <i>Sleep</i> , 1991, Vol. 14, pp. 511-516.	
	C20	EDWARDS, C.R. et al., "Dysfunction of placental glucocorticoid barrier: a link between the fetal environment and adult hypertension?", <i>Lancet</i> , Vol. 341, pp. 355-357, 1993.	
	C21	FRANK, A.L., "Injuries related to shiftwork", <i>Am J Prev Med</i> , 2000, Vol. 18, (45), pp. 33-36.	
	C22	GIBSON, E.S. et al., "The Impact of "Sleepiness" on Adolescent Students" Report of Population Health Grant 8555-15-1997-0000051, Health Canada, 1998-2002.	
V	C23	GIBSON, E.S. et al., "'Sleepiness' is serious in adolescence: Two surveys of 3235 Canadian students" <i>BMC Public Health</i> , 2006, Vol. 6, No. 116, pp. 1-9.	

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		First Named Inventor	Robert CASPER
		Art Unit	2873
		Examiner Name	Pinkney, D.
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/DP/	C24	GOLAND, R.S. et al., "Elevated levels of umbilical cord plasma corticotropin-releasing hormone in growth-retarded fetuses", <i>J Clin Endocrinol Metab</i> , Vol. 77, pp. 1174-1179, 1993.	
	C25	GUSTAFSSON, J.A. et al., "Sex steroid induced changes in hepatic enzymes", <i>Annu Rev Physiol</i> , Vol. 45, pp. 51-60, 1983.	
	C26	HAMMER, F. et al., "Cortisol metabolism in hypertension", <i>Best Pract Res Clin Endocrinol Metab.</i> , 2006, Vol. 20, pp. 337-53.	
	C27	HATTAR, S. et al., "Melanopsin and rod-cone photoreceptive systems account for all major accessory visual functions in mice", <i>Nature</i> , 2003, Vol. 424, pp. 76-81.	
	C28	HEALY, D. et al., "The circadian system and affective disorders: clocks or rhythms?", <i>Chronobiol Intern</i> , 1990, Vol. 7, pp. 5-9.	
	C29	HODDES, E. et al., "Quantification of sleepiness: A new approach", <i>Psychophysiol</i> , 1973, Vol. 10, pp. 431-436.	
	C30	HOROWITZ, T.S. et al., "Efficacy of bright light and sleep/darkness scheduling in alleviating circadian maladaptation to night work" <i>Am J Physiol Endocrinol Metab</i> , 2001, Vol. 281, pp. E384-E391.	
	C31	ISHIDA, A. et al., "Light activates the adrenal gland: Timing of gene expression and glucocorticoid release", <i>Cell Metab.</i> , 2005, Vol. 2, pp. 297-307 and Comment in: <i>Cell Metab.</i> , 2005, Nov, Vol. 2, No. (5), pp. 278-81.	
	C32	KAYUMOV, L. et al., "A randomized, double-blind, placebo-controlled crossover study of the effect of exogenous melatonin on delayed sleep phase syndrome", <i>Psychosom Med.</i> , 2001, Vol. 63, pp. 40-8.	
	C33	KAYUMOV, L. et al., "Blocking Low-Wavelength Light Prevents Nocturnal Melatonin Suppression with No Adverse Effect on Performance during Simulated Shift Work", <i>J Clin Endocrinol Metab.</i> , 2005, Vol. 90, pp. 2755-61.	
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		<b>Examiner Name</b>	Pinkney, D.
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/DP/	C34	KAYUMOV, L. et al., "Melatonin, sleep, and circadian rhythm disorders", <i>Semin Clin Neuropsychiatry</i> , 2000, Vol. 5, pp. 44-55.	
	C35	KHALSA, S.B. et al., "A phase response curve to single bright light pulses in human subjects" <i>J Physiol.</i> , 2003, Vol. 549, pp. 945-952.	
	C36	KRUPP, L.B. et al. "The fatigue severity scale. Application to patients with multiple sclerosis and systemic lupus erythematosus", <i>Arch. Neurol.</i> , 1989, Vol. 46, pp. 1121-1123.	
	C37	KUBO, T. et al., "Prospective Cohort Study of the Risk of Prostate Cancer among Rotating-Shift Workers: Findings from the Japan Collaborative Cohort Study", <i>Am J Epidemiol</i> , 2006, Vol. 164, No. 6 pp. 549-555.	
	C38	KUBOTA, T. et al., "Effects of nocturnal bright light on saliva melatonin, core body temperature and sleep propensity rhythms in human subjects", <i>Neurosci Res.</i> , 2002, Vol. 42, pp. 115-122.	
	C39	LINDSAY, R.S. et al., "Inhibition of 11-beta-hydroxysteroid dehydrogenase in pregnant rats and the programming of blood pressure in the offspring", <i>Hypertension</i> , Vol. 27, pp. 1200-1204, 1996.	
	C40	LINDSAY, R.S. et al., "Prenatal glucocorticoid exposure leads to offspring hyperglycaemia in the rat: studies with the 11 $\beta$ -hydroxysteroid dehydrogenase inhibitor carbenoxolone", <i>Diabetologia</i> , Vol. 39, pp. 1299-1305, 1996.	
	C41	LUNA, T.D., "Air Traffic Controller Shiftwork: what are the implications for aviation safety? A review", <i>Aviat Space Environ Med</i> , 1997, Vol. 68, pp. 69-79.	
	C42	MITLER, M.M. et al., "Catastrophes, Sleep, and Public Policy: Consensus Report", <i>Sleep</i> , 1988, Vol. 11, pp. 100-109.	
	C43	NEWNHAM, J.P. et al., "Maternal, but not fetal, administration of corticosteroids restricts fetal growth", <i>J Matern Fetal Med</i> , Vol. 8, pp. 81-87, 1999.	

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/DP/	C44	NOWAK, J.Z. et al., "Melatonin and its physiological and therapeutic properties", <i>Pharmacy World &amp; Science</i> , Vol. 20, No. 1, pp. 18-27, 1998.	
	C45	NYIRENDA, M.J. et al., "Glucocorticoid exposure in late gestation permanently programs rat hepatic phosphoenolpyruvate carboxykinase and glucocorticoid receptor expression and causes glucose intolerance in adult offspring", <i>J Clin Invest</i> , Vol. 15, pp. 2174-2181, 1998.	
	C46	OKAWA, M. et al., "Circadian rhythm sleep disorders in adolescents: clinical trials of combined treatments based on chronobiology", <i>Psychiatry Clin Neurosci</i> , 1998, Vol. 52, pp. 483-490.	
	C47	OWENS, J., "Insomnia in Children and Adolescents", <i>Journal of Clinical Sleep Medicine</i> , 2005, Vol. 1, pp. 454-458.	
	C48	PANDA, S. et al., "Coordinated transcription of key pathways in the mouse by the circadian clock", <i>Cell</i> , 2002, Vol. 109, pp. 307-320.	
	C49	PERREAU-LENZ, S. et al., "The Biological Clock: The Bodyguard of Temporal Homeostasis", <i>Chronobiology International</i> , 2004, Vol. 21, No. 1, pp. 1-25.	
	C50	PHELPS, J., "Dark therapy for bipolar disorder using amber lenses for blue light blockade", <i>Med Hypotheses</i> , 2008, Vol. 70, pp. 224-229.	
	C51	REINISCH, J.M. et al., "Prenatal exposure to prednisone in humans and animals retards intrauterine growth", <i>Science</i> , Vol. 202, pp. 436-438, 1978.	
	C52	REVELL, V. et al., "Alerting effects of light are sensitive to very short wavelengths", <i>Neuroscience Letters</i> , 2006, Vol. 399, pp. 96-100.	
	C53	RICHTER, H.G. et al., "The Circadian Timing System: Making Sense of day/night gene expression", 2004, <i>Biol Res</i> , Vol. 37, pp. 11-28.	

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/DP/	C54	Rosa RR, Bonnet MH, Bootzin RR, Eastman CI, Monk T, Penn PE, Tepas DI, Walsh JK. Intervention factors for promoting adjustment to nightwork and shiftwork. <i>Occup Med</i> 1995 5: 391-414.	
	C55	RUNNEBAUM, I.B. et al., "Glucocorticoids Inhibit Cell Death in Ovarian Cancer and Up-regulate Caspase Inhibitor cIAP2", <i>Clin Cancer Res</i> , 2005, Vol. 11, pp. 6325 - 6332.	
	C56	SCHREY, M.P. et al., "Bombesin and glucocorticoids stimulate human breast cancer cells to produce endothelin, a paracrine mitogen for breast stromal cells", <i>Cancer Research</i> , 1992, Vol. 52, pp. 1786-1790.	
	C57	SHANAHAN, T.L. et al., "Resetting the melatonin rhythm with light in humans", <i>J Biol Rhythms</i> , 1997, Vol. 12, pp. 556-67.	
	C58	SHIRAYAMA, M. et al., "The psychological aspects of patients with delayed sleep phase syndrome (DSPS)", <i>Sleep Med.</i> , 2003, Vol. 4, No. (5), pp. 427-433.	
	C59	SMITH, L. et al., "Increased injuries on night shift", <i>Lancet</i> , 1994, Vol. 344, pp. 1137-1139.	
	C60	SOOKOIAN, S. et al., "Effects of rotating shift work on biomarkers of metabolic syndrome and inflammation", <i>J Intern Med</i> , 2007, Vol. 261, pp. 285-292.	
	C61	STECKLER, T. et al., "Glucocorticoids and depression" <i>Baillieres Best Pract Res Clin Endocrinol Metab.</i> , 1999, Vol. 13, pp. 597-614.	
	C62	SUNTER, D., "Working Shift", Perspectives, Statistics Canada (Catalogue 75-001E), Spring 1993, pp. 16-23.	
	C63	THAPAN, A. et al., "An action spectrum for melatonin suppression: evidence for a novel non-rod, non-cone photoreceptor system in humans", <i>J Physiol</i> , 2001, Vol. 535, pp. 261-7.	
Examiner Signature	/Dawayne Pinkney/		Date Considered 11/17/2008

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PTO/SB/08b (10-07)

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Substitute for form 1449B/PTO		<b>Complete If Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		<b>Application Number</b>	101525,958
		<b>Filing Date</b>	October 20, 2005
		<b>First Named Inventor</b>	Robert CASPER
		<b>Art Unit</b>	2873
		<b>Examiner Name</b>	Pinkney, D.
		<b>Attorney Docket Number</b>	101648.55966US
(Use as many sheets as necessary)			
Sheet	8	of	9

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/DP/	C64	TUUNAINEN, A. et al., "Depression and endogenous melatonin in post menopausal women", <i>J Affect Disord.</i> , 2002, Vol. 69, No. (1-3), pp. 149-158.	
	C65	VAN DONGEN, H.P., "Shift work and inter-individual differences in sleep and sleepiness", <i>Chronobiol Int.</i> , 2006, Vol. 23, pp. 1139-47.	
	C66	VAN DONGEN, P.A. et al., "The cumulative cost of additional wakefulness: dose-response effects on neurobehavioral functions and sleep physiology from chronic sleep restriction and total sleep deprivation", <i>Sleep</i> , 2003, Vol. 26, No. 2, pp. 117-126.	
	C67	WARD, R.M. "Pharmacologic enhancement of fetal lung maturation", <i>Clin Perinatol.</i> , Vol. 21, pp. 523-542, 1994.	
	C68	WETTERBERG, L., "Clinical Importance of Melatonin", <i>Prog Brain Res.</i> , 1979, Vol. 52, pp. 639-4	
	C69	WETTERBERG, L., "Chapter 3. In: Shaffi M, Shaffi SL, eds. <i>Melatonin in adult depression</i> . Washington DC, MD", American Psychiatric Press Inc.; 1998, pp. 43-79.	
	C70	WHITMORE, J.N. et al., "Psychophysiological effects of a brief nocturnal light exposure", <i>J Hum Ergol.</i> , 2001, Vol. 30, pp. 267-72.	
	C71	WIRZ-JUSTICE, A. "Biological rhythm disturbances in mood disorders", <i>Int Clin Psychopharmacol.</i> 2006, Vol. 21 Suppl 1: S11-5.	
	C72	WOLFSON, A.R. et al., "Early school start times affect sleep and daytime functioning in adolescents", <i>Sleep Research</i> , 1996, Vol. 25, pp. 117.	
↓	C73	WOLFSON, A.R. et al., "Sleep schedules and daytime functioning in adolescents", <i>Child Dev</i> , 1998 Aug, Vol. 69, pp. 875-887.	

Examiner Signature	/Dwayne Pinkney/	Date Considered	11/17/2008
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